[OPTS-42063; TSN-FRL 2688-6]

Ethylene Bis(Oxyethylene) Diacetate; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice is EPA's response to the Interagency Testing Committee's (ITC) designation of ethylene bis(oxyethylene) diacetate (triethylene glycol diacetate, or TGD; CAS # 111-21-7) for priority consideration for health effects testing. The ITC did not recommend chemical fate or environmental effects testing for TGD. EPA is not initiating rulemaking at this time under section 4(a) of the Toxic Substances Control Act (TSCA) to require health effects testing of TGD. The Agency finds that available data are sufficient to reasonably determine or predict the effects on human health of TGD under its current conditions of manufacture and use. Because adequate information is available, further testing for health effects is not warranted for TGD at this time.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C. (554-1404), Outside the U.S.A.: (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is not initiating rulemaking at this time under section 4(a) of TSCA to require health effects testing of TGD as designated by the ITC in its Thirteenth Report.

I. Background

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established the ITC to recommend to EPA a list of chemicals to receive priority consideration for testing under section 4(a) of TSCA.

The ITC designated TGD for priority consideration in its Thirteenth Report, published in the Federal Register of December 14, 1983 (48 FR 55674). The designation was alkloxyethylene acetates, specificalaly TGD and 2-(2-butoxyethoxy)ethyl acetate. This notice constitutes EPA's response to the ITC's designation of TGD. The Agency is responding to the 2-(2-butoxyethoxy)ethyl acetate designation in a separate notice.

The ITC recommended that TGD be tested for subchronic toxicity, toxicokinetics, and reproductive effects. The rationale for recommending these tests was based on probable hydrolysis to a glycol ether (triethylene glycol) and concern about possible reproductive effects such as the lower molecular weigth glycol ether demonstrate.

Under section 4(a)(1) of TSCA, the Administrator shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the chemical may present an unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure, and release information to determine whether there is substantial production, and significant or substantial exposure or substantial release. Thus, while EPA can require testing for an effect under section 4(a)(1)(A) only if there is a suspicion of a hazard, under section 4(a)(1)(B) EPA can require testing whether or not there are data suggesting adverse effects if the relevant production and exposure or release criteria are met.

For the findings under both section 4(a)(1)(A)(ii) and section 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information. EPA's process for determining when these findings can be made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) finding is discussed in 45 FR 48528, and the section 4(a)(1)(B) finding is discussed in 46 FR 30300.

In evaluating the ITC's testing recommendations concerning TGD, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); and published and unpublished data available to the Agency, including information submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716).

II. Review of Available Data

A. Release and Exposure

Two companies currently manufacture TGD; they are Eastman Kodak Company, Eastman Chemicals Division in Kingsport, TN (Refs. 1 and 2), and Celanese Fibers Operations in Charlotte, NC (Ref. 3). Combined production by these two firms is between 1 and 10 million pounds annually (Ref. 2). CTC Organics, Inc., of Atlanta, GA, imports TGD from Japan (Refs. 4 and 5), apparently for resale in small lots.

TGD is produced in a closed system. Eastman Kodak states that approximately 50 workers are exposed to TGD for 75 hours per year (Ref. 2) during manufacturing operations; Celanese states that three persons per year are exposed. Because closed systems are employed and TGD is nonvolatile, EPA expects that these occupational exposures will be minimal.

The only known commercial use of TGD is as a plasticizer in the production of cigarette filter tips. This processing application is automated and expected to result in very little human exposure (Ref. 6).

Smokers will be exposed to TGD as it elutes from cigarette filters. EPA estimates that approximately 75 micrograms TGD will be eluted in mainstream smoke from a filter cigarette (Ref. 7). For a 60-kg person, who smokes 3 packs of filter cigarettes per day, these releases will result in inhalation exposures between 0.05 to 0.1 mg/kg/day.

Based upon information on production and use of TGD, releases to the environment are expected to be small. The ITC stated that it expected TGD to rapidly degrade in the environment. Based upon its own analysis, the Agency agrees with the ITC (Ref. 8).

B. Health Effects

No information on the biochemistry or *in vitro* effects of TGD could be located in the published literature, and none was submitted in response to the section 8(d) information gathering rule.

1. *Pharmacokinetics.* No studies specifically conducted on the pharmacokinetics of TGD are available. A metabolism study in rats submitted by Eastman Kodak (Refs. 9 and 10) indicates that TGD is rapidly absorbed from the gut, de-esterified, and excreted in the urine as triethylene glycol and metabolites of triethylene glycol.

2. *Acute toxicity.* The acute toxicity of TGD is low in rodents by all routes of administration. the intraperitoneal median lethal dose (LD_{50}) for the rat is 1,560 milligrams per kilogram (mg/kg) (Refs. 11 and 15). Reported values for the oral LD_{50}'s for the rat in three studies ranged from 14,300 to 25,100 mg/kg (Refs. 9, 11, 12, and 13). Oral LD_{50}'s for the mouse and rabbit are reported to be greater than 3,200 mg/kg (Refs. 1 and 14). A 6-hour inhalation LC_{50} in rats for an aerosol of TGD is reported to be greater than 6,100 mg/m^3 (Ref. 6). Dermal LD_{50}'s of TGD in rabbits and guinea pigs are 8,800 and 22,000 mg/kg (Refs. 11, 13, 14 and 15). TGD is reported to produce slight irritation to the skin and eye in the rabbit (Refs. 14 and 15). TGD is reported not to cause skin sensitization (Ref. 14).

3. *Subchronic toxicity.* EPA has received three subchronic studies on TGD in rats (Ref. 9). The first is a 90-day study which reported no observed effects in rats fed a diet containing 1,000 or 10,000 ppm TGD (approximately 60 or 600 mg/kg/day). The study included analyses of blood and urine samples taken on days 47 and 89 of the study and gross necropsy and histopathology immediately following cessation of dosing (day 90). The second is a 21-day gavage study where the animals were given doses of 7,000 mg/kg/day, 5 days per week, for a total of 14 doses. This dosage produced hydropic degeneration of the liver. No other effects were observed. The third is an inhalation study where rats were exposed to air saturated with TGD vapor (17 ppm or 163 mg/m^3) for 6 hours a day, 5 days a week, for a total of 22 exposures. No effects were observed in the study. The Agency believes that these studies are sufficient to demonstrate that TGD has a subchronic no-observed-effect-level of 600 mg/kg/day or more.

4. *Reproductive effects.* No studies characterizing the teratogenic or reproductive effects of TGD were submitted or found in the literature. However, the subchronic toxicity studies discussed above did not report any indication of adverse effects in gross and histopathological examinations of the reproductive organs (Ref. 9). Further, the primary metabolite of TGD, triethylene glycol, unlike lower molecular weight glycol ethers, was negative in a screen for reproductive toxicity effects (Ref. 16).

III. Decision Not To Initiate Rulemaking

EPA has decided not to initiate rulemaking at this time to require health effects testing of TGD under section 4(a) of TSCA. EPA believes that although substantial numbers of persons are exposed to small quantities of TGD through smoking filter cigarettes (see Unit II. A, above), existing data are sufficient to reasonably predict the effects of this exposure.

The Agency concludes that available data are sufficient to address the health effects testing concerns of the ITC for TGD when viewed in the light of the low levels of exposure to the substance. Toxicological studies on TGD submitted by Eastman Kodak are sufficient to conclude that present exposures to TGD will not result in subchronic toxicity. Although studies specifically designed to evaluate the reproductive effects of TGD are not available, EPA believes that it currently has sufficient information available to predict that present exposures to TGD will not result in adverse reproductive effects of TGD. First, TGD was not reported to have caused adverse effects in the reproductive organs in an available subchronic study. Second, while TCD does metabolize to triethylene glycol, available data indicate that triethylene glycol does not appear to cause reproductive effects (see Unit II.B.4, above). EPA's review of available information concerning TGD has revealed no basis for requiring testing for other health effects or for environmental fate or environmental effects.

IV. Public Record

EPA has established a public record for this decision not to test under section 4 of TSCA (docket number OPTS-42063). The record includes the following information:

A. Supporting Documentation

(1) Federal Register Notice containing the designation of TGD to the priority list and all comments on TGD received in response to that notice (48 FR 55674; December 14, 1983).

(2) Communications (public). (a) Letters. (b) Contact reports of telephone conversations. (c) Meeting summaries.

(3) Published and unpublished data.

B. References

(1) Eastman Kodak Company. (July 13). Eastman Chemicals Division, Kingsport, TN 37662. Triethylene glycol diacetate; ethylenebis (oxyethylene) diacetate. . . . Letter from C.Y. Brokaw to M. Greif, TSCA Interagency Testing Committee, Washington, D.C. 1982.

(2) Eastman Kodak Company. (Jan. 6). Eastman Chemicals Division, Kingsport, TN 37662. Letter from D.W. Kreh to TSCA Public Information Office, U.S. Environmental Protection Agency, Washington, D.C. 20460. 1984.

(3) Celanese. (Oct. 7). Celanese Fibers Operations, P.O. Box 32414, Charlotte, NC 28232. Ethylene bis (oxyethylene) diacetate. Letter from J.C. Pullen to L. Borghi, Dynamac Corporation, 11140 Rockville Pike, Rockville, MD 20852. 1983.

(4) Dynamac Corporation. (Feb. 6). 11140 Rockville Pike, Rockville, MD 20852. Memorandum to file from W. Bauer summarizing telephone conversations with J. Marriner, CTC Organics, Atlanta, GA, and R. Perez, Universal Preservachem, New York, NY. 1984.

(5) Dynamac Corporation. (Feb. 16). 11140 Rockville Pike. Rockville, MD 20852. Letter confirming telephone conversation from W. Bauer to J. Marriner, CTC Organics, Inc., PO. Box 6932, Atlanta, GA 30315. 1984.

(6) Celanese. (Aug.). Celanese Fibers Marketing Company. Product bulletin: Fiberset™ tow plasticizers. WSP 5.60 (a section of the manual "World Smoking Products"). Box 32414, Charlotte, NC 28232. 1978.

(7) Dynamac Corporation. (July). 11140 Rockville, MD 20852. Memorandum to file on consumer exposure to TGD in cigarette smoke. 1984.

(8) USEPA. (November, 20) U.S. Environmental Protection Agency. ENPART analysis of DGBA, TGD, oleylamine. Interagency Memorandum From R. Kinnenson to Test Rules Development Branch, Office of Toxic Substances. U.S. Environmental Protection Agency, Washington, D.C. 20460. 1984.

(9) Eastman Kodak Company. (Jan. 26). Eastman Chemicals Division, Kingsport, TN 37662. Letter from Robert L. Raleigh, MD, to Lynn Bradley, U.S. Environmental Protection Agency, Washington, D.C. 20460. 1984.

(10) McKennis, H., Turner, R.A., Turnbull, L.B., Bowman, E.R. "The excretion and metabolism of triethylene glycol," Toxicol Appl. Pharmacol. 4:411–431. 1962.

(11) "Patty's Industrial Hygiene and Toxicology," 3rd rev. ed. Vol. 2C. Clayton G.D., Clayton F.E., eds. New York: Wiley-Interscience, pp. 4007–4009, 4012–4014, 4028–4029. 1982.

(12) Smyth, H.F., Carpenter, C.P., Weil, C.S., Pozzani, U.C., Striegel, J.A., Nycum, J.S. "Range-finding toxicity data: list VII," Am. Ind. Hyg. Assoc. J. 30:470–476. 1969.

(13) Union Carbide Corporation. (Mar. 27). Technical data sheet: Toxicology studies. Triethylene glycol diacetate. Industrial Medicine and Toxicology Department, New York, NY 10017. 1969.

(14) Eastman Kodak Company. (Apr. 29) Material safety data sheet: Estrobond® G plasticizer. MSDS–10, 124A–4. Eastman Chemical Products, Inc., Kingsport, TN 37662. 1983.

(15) Union Carbide Corporation. Section 8(d) submission (Mar. 19, 1984) Jackson B. Browning to USEPA, docket OPTS–84009.

(16) Schuler, R.L., Hardin, B.D., Niemeier, R.W. et al. Results of testing fifteen glycol ethers in a short-term in vivo reproductive toxicity assay. Preprint. Paper presented at NIOSH Symposium on Toxic Effects. Cincinnati, OH: National Institute for Occupational Safety and Health. 1983.

This record includes basic information considered by the Agency in developing this notice, and is available from 8 a.m. to 4 p.m. Monday through Friday except legal holidays, in the OPTS Reading Room, Rm. E–107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement the record periodically with additional relevant information received.

(Sec. 4, Pub. L. 94–469, 90 Stat. 2000; (15 U.S.C. 2603))

Dated: November 8, 1984.

William D. Ruckelshaus,

Administrator.

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